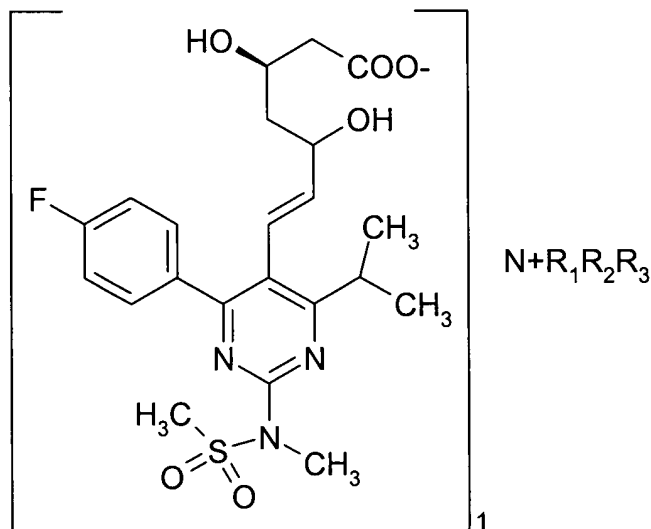


We Claim:

1. Amine salts of rosuvastatin of Formula I



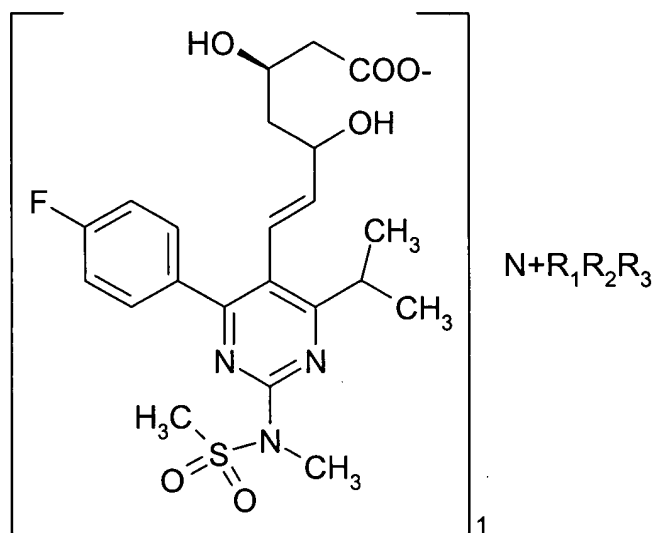
or solvate, hydrate, crystalline or amorphous form thereof, in which the amine residue has a Formula  $NR_1R_2R_3$  (wherein independently  $R_1$ ,  $R_2$  and  $R_3$  are H, straight or branched chain  $C_{1-15}$  alkyl or hydroxyalkyl,  $C_{3-10}$  single or fused ring optionally substituted cycloalkyl, optionally substituted aryl, optionally substituted aralkyl, alkylcycloalkyl, or independently  $R_1$ ,  $R_2$  and  $R_3$  combine with each other to form a  $C_{3-7}$  membered cycloalkyl ring or heterocyclic residue containing one or more heteroatoms), with the proviso that amine is not ammonia, methylamine, ethylamine, diethanolamine, tri(hydroxymethyl)-methylamine, benzylamine, or 4-methoxybenzylamine.

2. The amine salts of rosuvastatin of claim 1, having purity above 99% and diastereomeric impurity less than 0.5%.

3. The compound according to claim 2, wherein the purity is more than 99.5% and diastereomeric impurity less than 0.25%.

4. The compound according to claim 3, wherein the purity is more than 99.75% and diastereomeric impurity less than 0.15%.

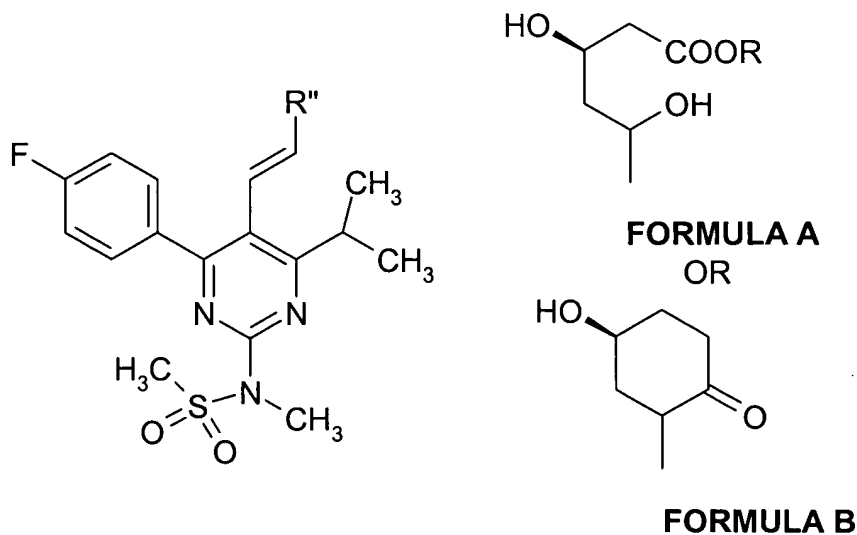
5. A process for the preparation of amine salts of rosuvastatin of Formula I



or solvate, hydrate, crystalline or amorphous form thereof, in which the amine residue has a Formula  $NR_1R_2R_3$  (wherein independently  $R_1$ ,  $R_2$  and  $R_3$  are H, straight or branched chain  $C_{1-15}$  alkyl or hydroxyalkyl,  $C_{3-10}$  single or fused ring optionally substituted cycloalkyl, optionally substituted aryl, optionally substituted aralkyl, alkylcycloalkyl, or independently  $R_1$ ,  $R_2$  and  $R_3$  combine with each other to form a  $C_{3-7}$  membered cycloalkyl ring or heterocyclic residue containing one or more heteroatoms), with the proviso that amine is not ammonia, methylamine, ethylamine, diethanolamine, tri(hydroxymethyl)-methylamine, benzylamine, or 4-methoxybenzylamine,

the process comprising:

a) treating rosuvastatin of Formula II

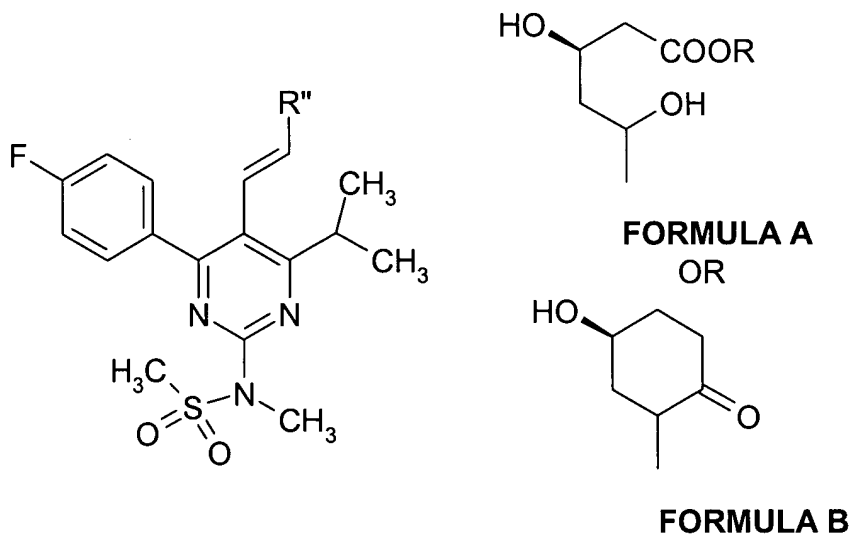


with an amine of Formula  $\text{NR}_1\text{R}_2\text{R}_3$  (wherein independently  $\text{R}_1$ ,  $\text{R}_2$  and  $\text{R}_3$  are H, straight or branched chain  $\text{C}_{1-15}$  alkyl or hydroxyalkyl,  $\text{C}_{3-10}$  single or fused ring optionally substituted cycloalkyl, optionally substituted aryl, optionally substituted aralkyl, alkylcycloalkyl, or independently  $\text{R}_1$ ,  $\text{R}_2$  and  $\text{R}_3$  combine with each other to form a  $\text{C}_{3-7}$  membered cycloalkyl ring or heterocyclic residue containing one or more heteroatoms), with a proviso that the amine is not selected from ammonia, methylamine, ethylamine, diethanolamine, tri(hydroxymethyl)-methylamine, benzylamine, or 4-methoxybenzylamine; and

b) isolating the amine salt of rosuvastatin of Formula I.

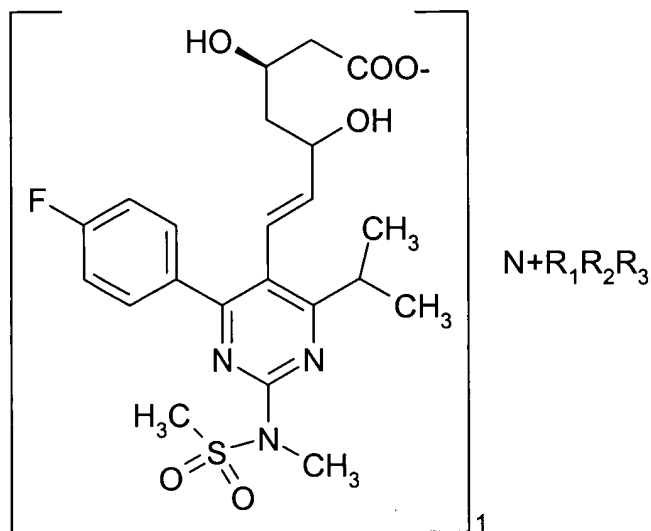
6. (Cancelled)

7. A process for preparation of amorphous or crystalline rosuvastatin calcium of Formula IIa from amine salt of Formula I,



wherein the process comprises of

a) treating an amine salt of Formula I,



or solvate, hydrate, crystalline or amorphous form thereof, in which the amine residue has a Formula  $NR_1R_2R_3$  (wherein independently  $R_1$ ,  $R_2$  and  $R_3$  are H, straight or branched chain  $C_{1-15}$  alkyl or hydroxyalkyl,  $C_{3-10}$  single or fused ring optionally substituted cycloalkyl, optionally substituted aryl, optionally substituted aralkyl, alkylcycloalkyl, or independently  $R_1$ ,  $R_2$  and  $R_3$  combine with each other to form a  $C_{3-7}$  membered cycloalkyl ring or heterocyclic residue containing one or more heteroatoms), with a proviso that the amine is not selected from ammonia, methylamine, ethylamine, diethanolamine, tri(hydroxymethyl)-methylamine, benzylamine, or 4-methoxybenzylamine, with an acid;

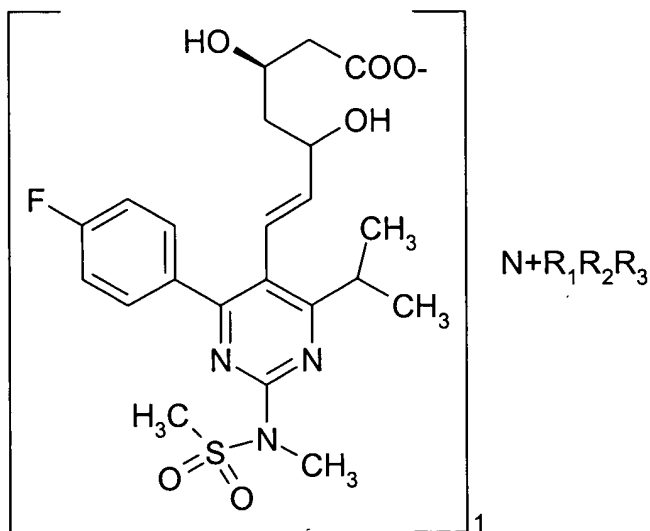
b) optionally isolating rosuvastatin acid or a lactone thereof;

c) adding a base and calcium ions;

d) isolating amorphous rosuvastatin calcium; and

e) optionally converting amorphous rosuvastatin calcium to crystalline rosuvastatin calcium.

8. A process for the preparation of amorphous rosuvastatin calcium from amine salt rosuvastatin of Formula I



or solvate, hydrate, crystalline or amorphous form thereof, in which the amine residue has a Formula  $NR_1R_2R_3$  (wherein independently  $R_1$ ,  $R_2$  and  $R_3$  are H, straight or branched chain  $C_{1-15}$  alkyl or hydroxyalkyl,  $C_{3-10}$  single or fused ring optionally substituted cycloalkyl, optionally substituted aryl, optionally substituted aralkyl, alkylcycloalkyl, or independently  $R_1$ ,  $R_2$  and  $R_3$  combine with each other to form a  $C_{3-7}$  membered cycloalkyl ring or heterocyclic residue containing one or more heteroatoms), with a proviso that the amine is not selected from ammonia, methylamine, ethylamine, diethanolamine, tri(hydroxymethyl)-methylamine, benzylamine, or 4-methoxybenzylamine,

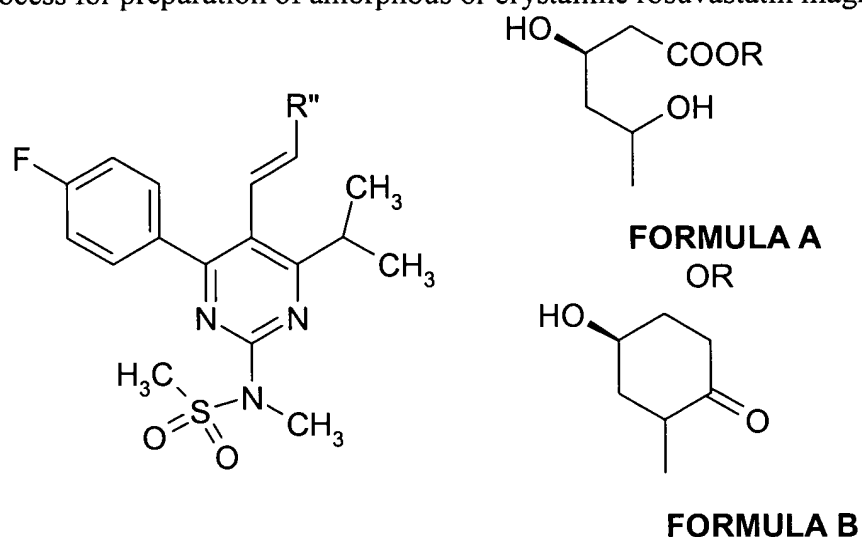
the process comprising

a) treating an amine salt of rosuvastatin with a base and a calcium ions; and

b) isolating the amorphous rosuvastatin calcium from the reaction mass.

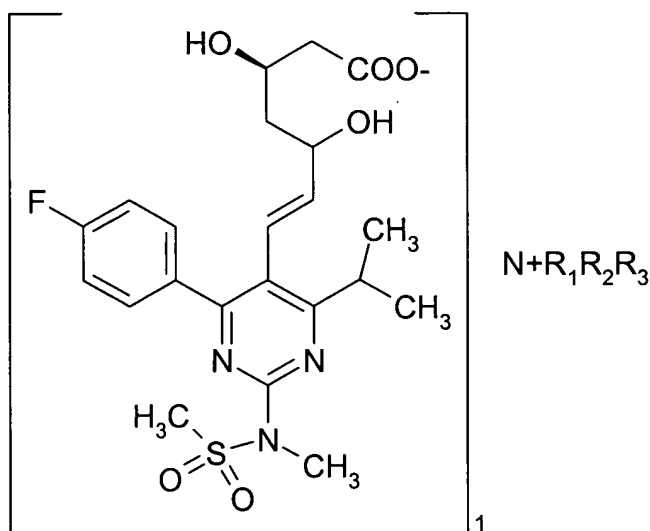
9. Amorphous rosuvastatin calcium prepared by a process according to claims 7 and 8 having a purity of at least above 99% having less than 0.5% of diastereomeric impurity.

1 10. A process for preparation of amorphous or crystalline rosuvastatin magnesium of



2 Formula IIb

3 from amine salt of Formula I,



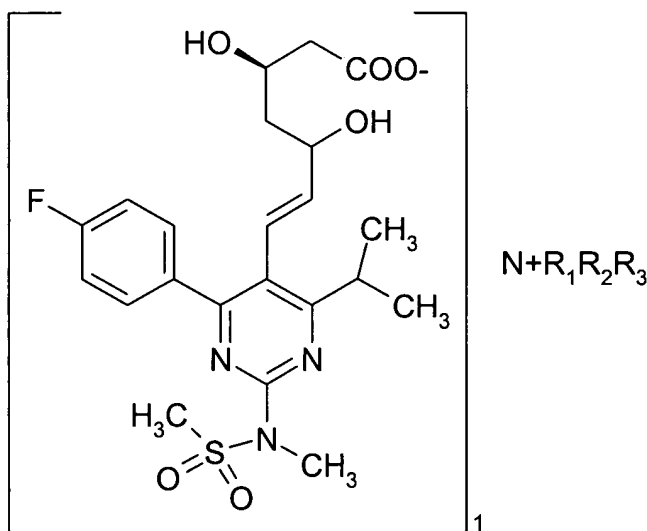
4  
5 or solvate, hydrate, crystalline or amorphous form thereof, in which the amine residue has a  
6 Formula NR<sub>1</sub>R<sub>2</sub>R<sub>3</sub> (wherein independently R<sub>1</sub>, R<sub>2</sub> and R<sub>3</sub> are H, straight or branched chain C<sub>1</sub>-  
7 15 alkyl or hydroxyalkyl, C<sub>3-10</sub> single or fused ring optionally substituted cycloalkyl,  
8 optionally substituted aryl, optionally substituted aralkyl, alkylcycloalkyl, or independently  
9 R<sub>1</sub>, R<sub>2</sub> and R<sub>3</sub> combine with each other to form a C<sub>3-7</sub> membered cycloalkyl ring or  
10 heterocyclic residue containing one or more heteroatoms), with a proviso that the amine is not  
11 selected from ammonia, methylamine, ethylamine, diethanolamine, tri(hydroxymethyl)-  
12 methylamine, benzylamine, or 4-methoxybenzylamine,

wherein the process comprises:

- a) treating an amine salt of Formula I with an acid;
- b) optionally isolating rosuvastatin acid or a lactone thereof;
- c) adding a base and magnesium ions;
- d) isolating crystalline rosuvastatin magnesium; and
- e) optionally converting crystalline rosuvastatin magnesium to amorphous rosuvastatin magnesium.

11. A process according to claim 10 wherein the acid is selected from inorganic mineral acids or organic acids.

12. A process for the preparation of amorphous rosuvastatin magnesium from amine salt of rosuvastatin of Formula I



or solvate, hydrate, crystalline or amorphous form thereof, in which the amine residue has a Formula  $NR_1R_2R_3$  (wherein independently  $R_1$ ,  $R_2$  and  $R_3$  are H, straight or branched chain  $C_{1-15}$  alkyl or hydroxyalkyl,  $C_{3-10}$  single or fused ring optionally substituted cycloalkyl, optionally substituted aryl, optionally substituted aralkyl, alkylcycloalkyl, or independently  $R_1$ ,  $R_2$  and  $R_3$  combine with each other to form a  $C_{3-7}$  membered cycloalkyl ring or heterocyclic residue containing one or more heteroatoms), with a proviso that the amine is not

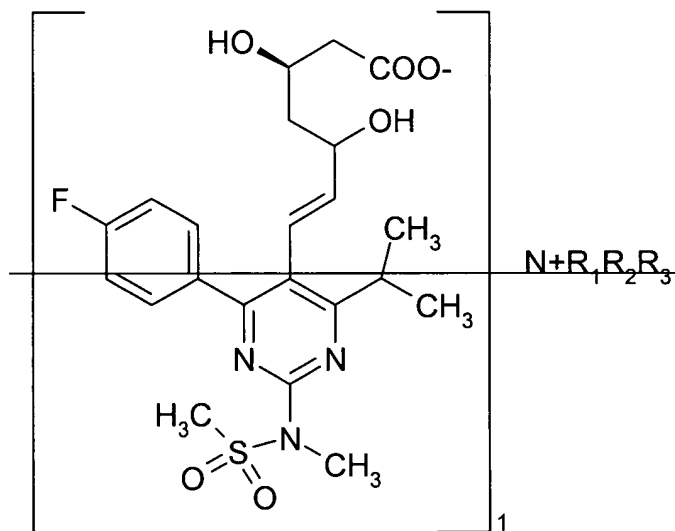
selected from ammonia, methylamine, ethylamine, diethanolamine, tri(hydroxymethyl)-  
methylamine, benzylamine, or 4-methoxybenzylamine,  
which comprises:

- a) treating an amine salt of rosuvastatin with a base and a magnesium ions; and
- b) isolating the crystalline rosuvastatin magnesium from the reaction mass.

13. Highly pure rosuvastatin calcium or rosuvastatin magnesium in crystalline or  
amorphous form thereof having purity of at least above 99.5% and diastereomeric impurity  
less than 0.25%.

14. – 23. (Cancelled)

24. (Currently Amended) A pharmaceutical composition comprising amine salts of  
rosuvastatin of Formula I according to claim 1.

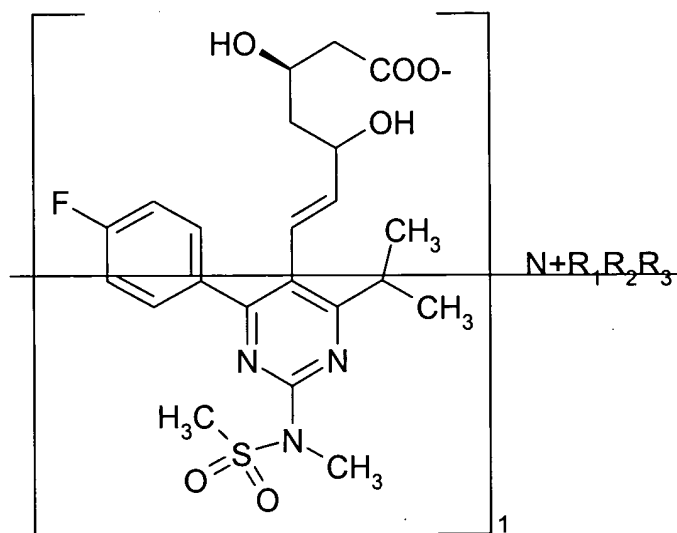


or solvate, hydrate, crystalline or amorphous form thereof, in which the amine residue has a  
Formula  $\text{NR}_1\text{R}_2\text{R}_3$  (wherein independently  $\text{R}_1$ ,  $\text{R}_2$  and  $\text{R}_3$  are H, straight or branched chain  $\text{C}_{1-15}$   
alkyl or hydroxyalkyl,  $\text{C}_{3-10}$  single or fused ring optionally substituted cycloalkyl,  
optionally substituted aryl, optionally substituted aralkyl, alkylcycloalkyl, or independently  
 $\text{R}_1$ ,  $\text{R}_2$  and  $\text{R}_3$  combine with each other to form a  $\text{C}_{3-7}$  membered cycloalkyl ring or  
heterocyclic residue containing one or more heteroatoms), with a proviso that the amine is not  
selected from ammonia, methylamine, ethylamine, diethanolamine, tri(hydroxymethyl)-



11 methylamine, benzylamine, or 4-methoxybenzylamine, with a pharmaceutically acceptable  
12 diluent or carrier.

1 25. (Currently Amended) A method of treating disease conditions wherein HMG-CoA is  
2 implicated, which comprises of administering to a mammal in need thereof a therapeutically  
3 effective amount of amine salt of rosuvastatin of Formula I according to claim 1.



4 or solvate, hydrate, crystalline or amorphous form thereof, in which the amine residue has a  
5 Formula  $NR_1R_2R_3$  (wherein independently  $R_1$ ,  $R_2$  and  $R_3$  are H, straight or branched chain  $C_{1-}$   
6  $_{15}$ -alkyl or hydroxyalkyl,  $C_{3-10}$ -single or fused ring optionally substituted cycloalkyl,  
7 optionally substituted aryl, optionally substituted aralkyl, alkylcycloalkyl, or independently  
8  $R_1$ ,  $R_2$  and  $R_3$  combine with each other to form a  $C_{3-7}$ -membered cycloalkyl ring or  
9 heterocyclic residue containing one or more heteroatoms), with a proviso that the amine is not  
10 selected from ammonia, methylamine, ethylamine, diethanolamine,  
11